IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Canfield, et. al.	
Serial No.: 10/601,723	Art Unit: 3762
Filed: 6/23/2003	
Title: HOUSING FOR AN IMPLANTABLE MEDICAL DEVICE	Examiner: Nicole R. Kramer
Attorney Docket No.: A279-USA	

DECLARATION OF GUANGQIANG JIANG, Ph.D.

Sir:

I, Guangqiang Jiang, declare that:

1) I am employed at the Alfred E. Mann Foundation for Scientific Research, with the title of Materials Scientist.

2) I have a Ph.D. from the University of Southern California with a major in Biomedical Engineering.

3) I am responsible for developing materials and processes in the creation of new biomedical products especially in the microstimulator / microsensor device field and am considered skilled and an expert in such field.

4) I was directly involved in the development of the housing for an Implantable Medical Device described in U.S. Patent Application Serial No. 10/601,723, which I have read and understand.

5) The design objective was to develop an overall housing that included an extremely small hollow tube, preferably cylindrical, formed of a magnetic field concentrating material such as ferrite and sized to house electronic circuitry in the tube's hollow portion, and to be implantable by means of a hypodermic needle type insertion tool.

6) I have read and understand U.S. Patent No. 4,071,032, which was cited against Application Serial No. 10/601,723 as the primary reference, and U.S. Patent No. 5,405,367, cited as a secondary reference.

7) I can say unequivocally that, I would not rely on nor use '032 as motivation nor suggestion nor as a technical source, even when considering '367, to teach a: "Housing for an Implantable Medical Device" as claimed, since '032 actually teaches away from the design objective recited above. The factual basis for my position is presented below.

8) Firstly, it is well understood that pacemakers, which are the devices repeatedly referenced as the subject of '032, are orders of magnitude larger in volume, and therefore size, than the claimed hollow cylindrical tube, consequently I would not use '032 as a guide or even starting point for the claimed tube. The shrinking in size of the device of '032 to accommodate the design objective would be so great as to render the use of the '032 patent as "counterproductive." Even if the size of the '032 device could be reduced, rather than a hollow cylindrical tube, it teaches a pacemaker shape, which would be completely unsuitable for implantation by a hypodermic needle type insertion tool.

9) Secondly, even if the size of the '032 device could be reduced, it would not perform or be implantable in a manner possible with the claimed hollow cylindrical tube. Schulman '032 teaches a pacemaker can formed of metal rather than a hollow cylindrical tube formed of ferrite. Immediately, this fact alone would disqualify '032 as providing a teaching that is contrary to the above design objective. There is no metal can forming a part of the hollow cylindrical tube. The '032 patent does teach that ferrite slabs or a ferrite coating can be used on the metal can, however neither a ferrite slab nor a coating in combination with the metal can, satisfies the "formed of" requirement imposed on the hollow cylindrical tube design.

10) Thirdly, if the ferrite slab or a coating were to be applied to the metal can of '032, having a thickness equivalent to the difference between the inside and outside diameters of the hollow cylindrical tube, the small size requirement of the hollow cylindrical tube would be severely compromised. Essentially, '032 teaches a two component rather than a one component device, the first component being the metal

can and the second component being the ferrite slab or the coating. The overall device size taught in '032 would therefore always be greater, due to the addition of the metal can dimension to the ferrite slab or coating, than is achievable with a single hollow cylindrical tube formed of ferrite. Accordingly, following the teachings of '032, would result in an increase of the tube size rather than the decrease of the tube size. The increased tube size would exacerbate the implant procedure, requiring, for example, a larger insertion tool, causing increased trauma at the insertion site and resulting in greater patient discomfort, which is contrary to the housing design objective.

11) The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

8/9/2006
Date

Guangqiang Jiang

http://www.sjm.com/devices/device.aspx?name=Frontier%26%23174%3B+II+CRT-P&location=us&type=24

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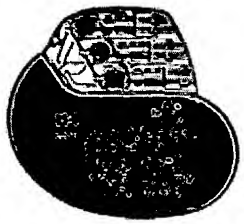
Frontier® II CRT-P

Approved for Use: United States

This device is approved for use in the United States.

The Frontier II device is St. Jude Medical's second commercially released low-voltage CRT-P device. The Frontier II device is designed to reduce the symptoms of moderate to severe heart failure (NYHA Class III or IV) in patients who are symptomatic despite stable, optimal medical therapy and who have prolonged QRS duration and left-ventricular EF < 35%. In addition, the Frontier II device is the only CRT-P device approved for patients who have undergone an AV nodal ablation for chronic atrial fibrillation and who have NYHA Class II or Class III heart failure.



Frontier II CRT-P
The Frontier II CRT-P device is designed to promote resynchronization and improve hemodynamic performance in patients with heart failure.

Select a link below to jump down the page:

- Biventricular pacing capabilities
- Advanced AT/AF diagnostics
- Atrial arrhythmia detection rate
- Stored electrograms

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Biventricular Pacing Capabilities

- Independently programmable RV and LV amplitudes and pulse widths enable the customization of energy requirements to assist in more appropriate capture of both ventricles
- Triggered modes help to ensure continuous therapy delivery
- Negative AV/PV hysteresis provides a self-regulating means by which to shorten the programmed AV/PV delay when a sensed ventricular event occurs during the AV/PV delay interval. This algorithm promotes a high percentage of ventricular stimulation, which is important for the maintenance of synchrony of left and right ventricles.

APPENDIX B

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Advanced AT/AF Diagnostics

- AT/AF burden trend provides a graphical representation of the percentage of time in AT/AF and the number of AT/AF episodes for the previous 28 weeks. This diagnostic view can help identify long-term trends related to the time or episodes in AT/AF. The AT/AF burden trend event counter identifies a historical trend for device or drug management and provides specific tabular data on the number of episodes, duration, and percent of time per week the patient was in AT/AF.
- AT/AF episodes log lists up to 32 recorded AT/AF episodes in the order of occurrence with each episode's date and time, total AT/AF episodes, and percent of time in AT/AF. This specific episode data helps provide insight into the patient's arrhythmias and shows whether the episodes are occurring more frequently or lasting longer over time.
- AT/AF episode histogram provides a broad picture for speedy diagnosis and improves patient management by reporting episode rate and duration data
- AT/AF detection trigger provides an EGM snapshot of AT/AF episodes, determines efficacy of therapy, and displays atrial and ventricular rhythm

Atrial Arrhythmia Detection Rate

- Far-field protection and atrial absolute refractory period provides enhanced atrial arrhythmia detection and AT/AF diagnostics, and allows more accurate mode switch events
- Atrial protection interval offers enhanced protection against competitive atrial pacing

Stored Electrograms

Real-time EGMs provide up to 120 seconds of real-time electrocardiograms to help in the identification of key intrinsic and pacemaker-related events and could simplify the diagnosis of complex ECG rhythms associated with heart failure.

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Model

Frontier II 5586

IS-1 connector
25 g
11.5 cc
6 mm
Negative AV/PV hysteresis with search
AT/AF diagnostic suite

Stored electrograms

View Indications, Contraindications, Warnings, Precautions & Potential Adverse Events.

http://www.sjm.com/devices/device.aspx?name=Affinity%26%23153%3B+Pacemaker&location=us&type=2

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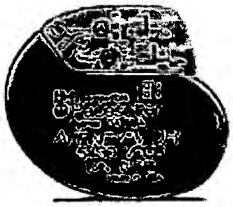
Affinity™ Pacemaker

Approved for Use: United States & International

This device is approved for use in the United States and internationally.

The Affinity pacemaker family offers some of today's smallest, truly automatic devices. Featuring the most effective combination of advanced technologies ever seen, the Affinity DR pacemaker incorporates the exclusive ventricular AutoCapture™ Pacing Systems, assuring Beat-by-Beat™ capture.



Affinity Pacemaker

Models: Affinity DR, Affinity VDR, Affinity SR, & Affinity DC.

Offers some of today's smallest, truly automatic devices.

The family includes the clinically proven Omnisense™ Accelerometer Sensor, featuring an auto rest rate (based on activity rather than on preset clock settings) and auto rate response.

Other automatic rate-responsive features include:

- Hysteresis rate and rate hysteresis search
- Autointrinsic conduction search
- Negative AV/PV hysteresis with search

Additional features include:

- Auto mode switching
- Post-ventricular atrial blanking
- PMT options
- PVC options
- Ventricular blanking
- Ventricular safety standby

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The Affinity VDR pacemaker combines the advanced features of the popular Affinity product family with the easy-to-use, streamlined single-pass pacing configuration. It is recommended that the Affinity VDR atrial-ventricular pacing system be used with St. Jude Medical's AV Plus lead to provide A-V synchronous pacing.

Models

Select a link below to jump down the page

- Affinity® DR Pacemakers
- Affinity® VDR Pacemaker
- Affinity® SR Pacemakers
- Affinity® DC Pacemakers

Affinity DR Pacemakers

Affinity DR 5330L
Left-sided, IS-1/VS.1 compatible
23.5 g, 11 cc, 6 mm thin
Beat-by-Beat AutoCapture Pacing Systems
Omnisense accelerometer sensor
Auto rest rate
Auto mode switch
Multiple automated feature sets

Affinity DR 5330R
Right-sided, IS-1/VS.1 compatible
23.5 g, 11 cc, 6 mm thin
Beat-by-Beat AutoCapture Pacing Systems
Omnisense accelerometer sensor
Auto rest rate
Auto mode switch
Multiple automated feature sets

Affinity DR 5331 M/S
5/6 mm connector
23.5 g, 11 cc, 6 mm thin
Omnisense accelerometer sensor
Auto rest rate
Auto mode switch
Multiple automated feature sets

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Affinity VDR Pacemaker

Affinity VDR 5430
Uncoated, right- or left-sided, IS-1/VS.1 compatible
23.5 g, 11 cc, 6 mm thin
Beat-by-Beat AutoCapture Pacing Systems
Omnisense accelerometer sensor
Auto rest rate
Auto mode switch
Multiple automated feature sets

Affinity SR Pacemakers

Affinity SR 5130L
Left-sided, IS-1/VS.1 compatible
23 g, 10.4 cc, 6 mm thin
Beat-by-Beat AutoCapture Pacing Systems
Omnisense accelerometer sensor

Auto rest rate

Affinity SR 5130R
Right-sided, IS-1/VS.1 compatible
23 g, 10.4 cc, 6 mm thin
Beat-by-Beat AutoCapture Pacing Systems
Omnisense accelerometer sensor
Auto rest rate

Affinity SR 5131 M/S
5/6 mm connector
23 g, 10.4 cc, 6 mm thin
Omnisense accelerometer sensor
Auto rest rate

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Affinity DC Pacemakers

Affinity DC 5230L
Left-sided, IS-1/VS.1 compatible
23.5 g, 11 cc, 6 mm thin
Beat-by-Beat AutoCapture Pacing Systems
Auto rest rate
Auto mode switch
Multiple automated feature sets

Affinity DC 5230R
Right-sided, IS-1/VS.1 compatible
23.5 g, 11 cc, 6 mm thin
Beat-by-Beat AutoCapture Pacing Systems
Auto rest rate
Auto mode switch
Multiple automated feature sets

Affinity DC 5231 M/S
5/6 mm connector
23.5 g, 11 cc, 6 mm thin
Auto rest rate
Auto mode switch
Multiple automated feature sets

View Indications, Contraindications, Warnings, Precautions & Potential Adverse Events.

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http://www.sjm.com/devices/device.aspx?name=Identity%26%23174%3B+Pacemaker&location=us&type=2

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Identity® Pacemaker

Approved for Use: United States & International

This device is approved for use in the United States and internationally.

The Identity pacemaker family, which includes the world's smallest dual-chamber pacemaker, provides clinicians with the most advanced pacemaker technology available, including the revolutionary AF Suppression™ algorithm, the first and only U.S. commercially approved algorithm designed to suppress atrial fibrillation (AF). The AF Suppression algorithm in the Identity pacemaker family is combined with the most advanced diagnostic systems and bradycardia feature set available today, establishing the Identity pacemaker as the premier product offering in complete arrhythmia care.

Identity Pacemaker

Models: Identity DR, Identity XL, & Identity SR
Features an AF Suppression algorithm designed to suppress atrial fibrillation (AF).

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The Identity pacemaker models 5370 and 5376 feature AF management, a suite of therapeutic and diagnostic capabilities designed to manage pacemaker patients suffering from AF. This tool kit includes:

- **AF Suppression Algorithm** - Clinically proven and designed to suppress AF before it happens
- **AF Histogram** - Allows you to evaluate the success of the AF suppression algorithm
- **Stored Electrograms** - Provides a comprehensive overview of patient-device interactions, especially high atrial rate activity
- **Auto Mode Switch (AMS) Log** - Stores rate and duration information for mode switch episodes
- **Separately Programmable AMS Base Rate** - Addresses drastic mode switching rate variations for improved patient comfort
- **Physician Commanded Atrial Therapy (NIPS - Non-Invasive Programmed Stimulation)** - Provides the clinician with another option in the treatment of atrial arrhythmias

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The Identity pacemaker family also encompasses the most advanced bradycardia feature set, including the

exclusive ventricular AutoCapture™ Pacing Systems, assuring Beat-by-Beat™ capture management and a projected longevity of 12.6 years.[1]

Other features available in the Identity pacemaker family include:

- **Advanced Hysteresis Response** - Manages special rate situations including abrupt rate drop
- **Automatic P & R Wave Measurements** - Provides accuracy and speed in follow-up
- **Omnisense® Accelerometer Sensor** - Provides appropriate and prompt rate response for your patient's activity level
- **Auto Rest Rate** - Provides patient comfort during periods of inactivity and rest
- **Cross Sensor AMS** - Offers cross sensor mode switching (such as DDDR to DDI) when sensor is programmed on
- **Onscreen Help** - Offers viewing capabilities of the software reference manuals on the programmer by selecting the Help button on the programmer console
- **Previous Test Results** - Records the results from the last sense or capture test in the pacemaker memory
- **Remaining Longevity Estimate** - Gives an estimate of the remaining life of the device

[1]Identity XL 5376 DDDR, AutoCapture Pacing Systems on, 100% pacing, 60 bpm, 0.4 ms, 2.5 V atrium, 1.0 V ventricle, 500 ohm

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Models

Select a link below to jump down the page:

- Identity DR 5370
- Identity XL 5376
- Identity SR 5172

Identity DR 5370

World's smallest dual-chamber, rate-responsive pacemaker
43 x 44 x 6 mm, 18 g, and 8 cc
AF Suppression algorithm
AF histogram
Stored electrograms (EGMs)
Automatic mode switch (AMS) log
Programmable auto mode switch (AMS) base rate
Physician commanded atrial therapy (NIPS - Non-Invasive Programmed Stimulation)
Beat-by-Beat AutoCapture Pacing Systems
Omnisense accelerometer sensor
Connector that accepts all unipolar and bipolar IS-1 3.2 mm short terminal pin leads
Automatic P & R wave measurements
Advanced hysteresis response
Cellular Tested™

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Identity XL 5376

Dual-chamber, rate-responsive pacemaker
44 x 52 x 6 mm, 23.5 g, and 11 cc
AF Suppression algorithm
AF histogram
Stored electrograms (EGMs)
Automatic mode switch (AMS) log
Programmable auto mode switch (AMS) base rate
Physician commanded atrial therapy (NIPS - Non-Invasive Programmed Stimulation)
Beat-by-Beat AutoCapture Pacing Systems
Omnisense accelerometer sensor
Connector that accepts all unipolar and bipolar VS-1 or IS-1 3.2 mm leads
Automatic P & R wave measurements
Advanced hysteresis response
Cellular Tested

[1]Identity XL 5376 DDDR, AutoCapture Pacing System on, 100% pacing, 60 bpm, 0.4 ms, 2.5 V atrium, 1.0 V ventricle, 500 ohm

Identity SR 5172

Single-chamber, rate-responsive pacemaker
41 x 44 x 6 mm, 17 g, and 8 cc
Stored electrograms (EGMs)
Beat-by-Beat AutoCapture Pacing Systems
Omnisense accelerometer sensor
Connector that accepts all unipolar and bipolar IS-1 3.2 mm short-terminal pin leads
Automatic P & R wave measurements
Advanced hysteresis response
Cellular Tested

View Indications, Contraindications, Warnings, Precautions & Potential Adverse Events.

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